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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,144	01/30/2004	Tibor Keler	CDJ-301RCE	9318

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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
04/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/769,144	KELER ET AL.	
	Examiner	Art Unit	
	YUNSOO KIM	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-36,39-44,47-52 and 55-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-36,39-44,47-52 and 55-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 33-36, 39-44, 47-52 and 55-59 are pending.

2. In light of Applicants' amendment to claims filed on 12/20/07, the rejections of record set forth in the office action mailed 7/26/07 have been withdrawn.

3. The following new rejection is necessitated by Applicants' amendments filed on 11/19/07.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 33-36, 39-44, 47-52 and 55-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/85798 (IDS reference, of record) in view of U.S. Pat. No. 5,869,057 (IDS reference, of record).

The '798 publication teaches a method of inducing an immune response with a molecular conjugate (e.g. complex) and a composition comprising an human monoclonal antibody to antigen presenting cell (e.g. dendritic cell) conjugated to a tumor antigen (p. 5-6, 54-55, claims, 33-42) and the immunostimulatory cytokines (i.e. IL-2 or IFN-γ, p. 57). The '798 publication

teaches that the monoclonal antibody that binds to APC binds to the macrophage mannose receptor (claim 5).

The '798 publication further teaches that the anti-APC antibody, tumor antigen and the molecular conjugate can be conjugated with an immunomodulatory cytokine covalently, genetically or recombinantly as a fused protein (p. 44, 54, 55 and p. 5).

Moreover, the '798 publication teaches *in vivo and ex vivo* internalization of antigen by APC, immune response mediated by MHC-I/II complexes, cytotoxic Tcell, and CD4+ and CD8+ cells, and the antibody being Fab or scFv (p. 5-6, 26, 35, 36, 38-41, 56-58, claims 5, 16, 23-27, 32, 38-42, in particular).

In addition, the '798 publication teaches that the antibody having claimed SEQ ID NOs:4 and 8 (Fig. 13, B11 V_L and B11 V_H proteins). As the claimed SEQ ID NOs:4 and 8 encompass CDRs identified as in SEQ ID NOs:13-18, claims 41-43 are included in this rejection.

The '798 publication does not teach the use of βhCG as an antigen as in claim 1.

However, the '057 patent teaches the use of βhCG as an antigen (i.e. detectable on the 74 cancer cell lines, col. 3, lines 40-50, col. 5, lines 32-60, in particular). The '057 patent further teaches that the βhCG is expressed and detectable on the surface of all tumor cells and could be used in immunization against βhCG and an antimetastasis treatment.

It would have been obvious to one of the ordinary skill in the art at the time the invention was made to employ βhCG as a tumor antigen as taught by the '057 patent into the molecular conjugate comprising a human monoclonal antibody that binds to dendritic cells and immunostimulatory cytokine taught by the '798 publication.

One of the ordinary skill in the art would have been motivated to do so because of the well known characteristics of βhCG as a tumor antigen in treatment and its availability on all known tumor cells as taught by the '057 patent (col. 3, col. 5, in particular).

From the teachings of references, it would have been obvious to one of the ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary skill in the art at the time of invention was made, as evidenced by references, especially in the absence of evidence to the contrary.

Applicants' arguments filed on 12/20/07 have been fully considered but they were not persuasive.

Applicants' traversed the rejection based on that the primary reference ('798 publication) does not teach the use of βhCG and the antigens as recited in claim 1 and the '057 patent fails to teach the use of antibody as in the claimed invention.

Applicants further argued that the prior art had not shown the claimed CTL response could be predicted or mediated by both MHC Class I and Class II pathways and intracellular pathways for MHC Class I and II presentations.

As discussed above, the CTL response mediated by CD4+ and CD8+ T cells and MHC-I/II complexes are taught throughout the '798 publication and such immune response are achieved by the molecular conjugation of monoclonal antibody that binds to the macrophage mannose receptor on APC and a tumor antigen. The '057 patent provides the motivation to select the βhCG as a tumor antigen because it is expressed and detectable on the surface of all tumor cells. The βhCG is used in immunization as well as antimetastasis treatment (col. 3, lines 40-50, col. 5, lines 32-60).

Given that the obviousness does not require absolute predictability but only the reasonable expectation (MPEP 2143.02) and one cannot show nonobviousness by attacking references individually (MPEP 2145), the claimed invention remains obvious.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. No claims are allowable.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on M-F,9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim
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Technology Center 1600
April 4, 2008
/ILIA OUSPENSKI, Ph.D./

Primary Examiner, Art Unit 1644